

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 1248	Date: MAY 25, 2007
	Change Request 5520

SUBJECT: Revisions, in the Medicare Claims Processing Manual, to Section 40, titled, "Discarded Drugs and Biologicals," and Section 100.2.9, titled, "Submission of Claims With the Modifier JW, 'Drug Amount Discarded/Not Administered to Any Patient.'"

I. SUMMARY OF CHANGES: The manual section will be revised to include language that references both single use vials and single use packages for discarded drugs and biologicals.

New / Revised Material

Effective Date: July 1, 2007

Implementation Date: July 2, 2007

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	Chapter / Section / Subsection / Title
R	17/40/Discarded Drugs and Biologicals
R	17/100.2.9/Submission of Claims with the Modifier JW, "Drug Amount Discarded/Not Administered to Any Patient"

III. FUNDING:

No additional funding will be provided by CMS; Contractor activities are to be carried out within their FY 2007 operating budgets.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

**Unless otherwise specified, the effective date is the date of service.*

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A / B M A C	D M E M A C	F I I E R	C A R R I E R	D M R R C	R H I	E D C	Shared-System Maintainers			
								F I S S	M C S	V M S	C M S	
	notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.											

IV. SUPPORTING INFORMATION

A. For any recommendations and supporting information associated with listed requirements, use the box below: N/A

Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

B. For all other recommendations and supporting information, use this space: N/A

V. CONTACTS

Pre-Implementation Contact(s): Glenn McGuirk, glenn.mcguirk@cms.hhs.gov

Post-Implementation Contact(s): Appropriate Regional Office

VI. FUNDING

A. For TITLE XVIII Contractors, use only one of the following statements:

No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2007 operating budgets.

B. For Medicare Administrative Contractors (MAC), use the following statement:

The contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the Statement of Work (SOW). The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

40 - Discarded Drugs and Biologicals

(Rev. 1248, issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

The CMS encourages physicians, hospitals and other providers to schedule patients in such a way that they can use drugs *or biologicals* most efficiently, *in a clinically appropriate manner*. However, if a physician, hospital or other provider must discard the remainder of a *single use* vial or other *single use* package after administering a dose/quantity of the drug or biological to a Medicare patient, the program provides payment for the amount of drug *or biological* discarded along with the amount administered, *up to the amount of the drug or biological as indicated on the vial or package label*.

Please see subsection 100.2.9 - Submission of Claims With the Modifier JW, “Drug *or Biological* Amount Discarded/Not Administered to Any Patient”, for additional discussion of the discarded remainder of a vial or other packaged drug *or biological* in the CAP.

NOTE: Multi-use vials are not subject to payment for discarded amounts of drug *or biological*.

EXAMPLE 1:

A provider schedules three Medicare patients to receive Botulinum Toxin Type A on the same day within the designated shelf life of the product. Currently, Botox is available only in a 100-unit size. Once Botox is reconstituted, it has a shelf life of only four hours. Often, a patient receives less than a 100 unit dose. The provider administers 30 units to each of the three patients. The remaining 10 units that must be discarded are billed to Medicare on the account of the last patient. Therefore, 30 units are billed on behalf of the first patient seen and 30 units are billed on behalf of the second patient seen. Forty units are billed on behalf of the last patient seen because the provider had to discard 10 units at that point.

EXAMPLE 2:

A provider administers 15 units of Botulinum Toxin Type A to a Medicare patient, and it is not practical to schedule another patient who requires Botulinum Toxin. The remaining 85 units are discarded. For example, the provider may have only one patient who requires Botulinum Toxin, or the patient requiring treatment may be previously unknown to the provider, thereby precluding consideration of the treatment modality in scheduling the new patient. The provider bills for 100 units on behalf of the patient and Medicare pays for 100 units.

100.2.9 - Submission of Claims With the Modifier JW, “Drug Amount Discarded/Not Administered to Any Patient”

(Rev. 1248, issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

Chapter 17, Section 40 – Discarded Drugs and Biologicals, provides Medicare payment policy for the discarded remainder of a single use drug *or biological* product after administering it to a Medicare patient, *up to the amount of the drug or biological indicated on the vial or package label*. This policy will apply equally to drugs priced through ASP and drugs included in the CAP.

If the participating CAP physician has made a good faith effort to minimize the unused portion of the CAP drug *or biological* in how he or she scheduled patients and how he or she ordered, accepted, stored, and used the drug *or biological*, and only if the approved CAP vendor has made good faith efforts to minimize the unused portion of the drug *or biological* in how it supplied the drug *or biological* to the participating CAP physician, then the program will cover the amount of drug *or biological* discarded along with the amount administered.

Any contractor that is currently applying any local unused drug *or biological* (wastage) policy that requires a separate detail line with the unused drug modifier (JW) to indicate billing for the unused portion of a single-use drug *or biological* product as per Chapter 17 Section 40-Discarded Drug and Biologicals, may continue to apply the policy for CAP. These carriers shall accept the CAP J codes on the same line as the JW modifier as required in Section 100.2.1 to indicate that the claim for the unused drug *or biological* is for a CAP drug. Each line with a JW modifier must have either a J1- “no-pay” modifier or a J3 –“furnish as written” modifier:

J1 + JW

J3 + JW